

Notice of Allowability

Application No.

10/004,987

Examiner

Charles A. Marmor, II

Applicant(s)

BURBANK ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed 28 December 2004 and the telephonic interview of 02 February 2005.
2. ☒ The allowed claim(s) is/are 65,67-76 and 78-91.
3. ☒ The drawings filed on 11 December 2002 and 07 March 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

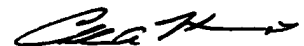
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 02022005.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Charles A. Marmor, II
Primary Examiner
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EXAMINER'S AMENDMENT

1. This Office Action is responsive to the Amendment filed December 28, 2004. The Examiner acknowledges the amendments to claims 1, 53-59, 65, 67, 68, 73, 74, 78, 79, 83-85 and 91, as well as the cancellation of claims 93-95. Claims 1, 49, 52-61, 65, 67-76 and 78-92 are pending.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Edward J. Lynch on February 2, 2005.

3. The application has been amended as follows:
- a. Claim 1 has been canceled.
 - b. Claim 49 has been canceled.
 - c. Claims 52-61 have been canceled.
 - d. In claim 65, line 11, "and" has been deleted.
 - e. In claim 68, lines 11 and 15, "desired" has been deleted.

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f. Claim 70 has been amended as follows:

70. (Currently Amended) The medical device of claim 68, wherein the free ends of said fixation ~~element is~~ elements are configured for penetrating tissue at the target site.

g. In claim 71, line 2, “element which has” has been changed to --elements have--.

h. In claim 72, line 2, -- first and second -- has been inserted before “fixation”.

i. In claim 75, line 2, -- first and second -- has been inserted before “fixation”.

j. In claim 78, line 2, “shaft portion” has been changed to --end of the shaft--.

k. Claim 79 has been amended as follows:

79. (Currently Amended) A medical device for localization of tissue at a target site comprising:

a shaft having a distal portion with a distal tip, and being configured for placement of said distal ~~[[end]]~~ portion into a patient's body at a desired location;
a distal cutting element disposed on said distal tip;
a radially expandable side-cutting element configured for cutting a tissue sample from target tissue and disposed on said shaft proximal of said distal tip; and
a fixation element which has a free end, which is disposed on said distal portion proximal of said distal tip and which is configured for securing the distal ~~[[end]]~~ portion of said medical device within tissue at the target site.

l. Claim 84 has been amended as follows:

84. (Currently Amended) The medical device of claim ~~[[83]]~~ 79, wherein said fixation element comprises a plurality of radially extendable and retractable members which are radially extendable and retractable from a side of the distal ~~[[end]]~~ portion of the shaft, and which have free ends configured for securing the distal ~~[[end]]~~ portion of the shaft adjacent target tissue.

m. Claim 92 has been canceled.

4. The terminal disclaimer filed on December 28, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,312,429; 6,540,693; 6,540,695; 6,638,234; 6,679,851; and 6,716,179 has been reviewed and is accepted. The terminal disclaimer has been recorded.

5. The following is an examiner's statement of reasons for allowance:

Regarding claims 65 and 67, no prior art of record teach or fairly suggest a method for acquiring a tissue specimen from a target site by placing the distal end of a shaft of a tissue acquisition device that has a distal cutting element disposed on a distal tip of the shaft and a distal shaft portion with at least one first fixation element which extends away from the distal shaft portion in a proximal direction and at least one second fixation element which extends away from the distal shaft portion in a distal direction in a patient's body such that the distal tip is distally adjacent to a target site, extending the fixation elements into tissue at the target site to secure the distal end of the shaft within the target site, and separating a tissue specimen at the target site.

Regarding claims 68-75, no prior art of record teach or fairly suggest a medical device for localization of tissue at a target site and a method for use thereof, where the device includes a shaft with a distal tip, a radially expandable side-cutting element disposed on a distal shaft portion proximal to the distal tip with an expanded configuration for cutting tissue; a first

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fixation element which extends away from the distal shaft portion in a proximal direction; and a second fixation element which extends away from the distal shaft portion in a distal direction.

Regarding claims 76 and 78-91, no prior art of record teach or fairly suggest a medical device for localization of tissue at a target site and a method for use thereof, where the device includes a shaft having a distal tip with a distal cutting element, a radially expandable side-cutting element disposed on a distal shaft portion proximal to the distal tip with an expanded configuration for cutting tissue; and a fixation element disposed on the distal shaft portion proximal of the distal tip for securing the distal end of the device within target tissue.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
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February 2, 2005